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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
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09/454,252 12/02/99 PELLETIER

J 248/037

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HM22/0313

EXAMINER

TU, S

ART UNIT

PAPER NUMBER

1653

DATE MAILED:

03/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/454,252

Applicant(s)

PELLETIER ET AL.

Examiner

Stephen Tu

Art Unit

1653

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9 and 36-99 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 9, and 36-99 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

The Amendment and Response filed 14 December 2000 has been received. Claim 9 has been amended, Claims 1, 16, 19, 21-23, 25-27, 32, 33, and 35 have been canceled, and new Claims 36-99 added. Thus, Claims 9, and 36-99 are pending in the application. The following is applicable to the pending claims.

Election/Restrictions

1. Applicants' election of Claim 9, with traverse, in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Applicants have added new Claims 36-99, which are drawn to different, patentably distinct inventions. Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claims 36-37, 61-64, 93-99 drawn to a method of identifying a target for antibacterial agents via protein binding, classified in class 435, subclass 7.1.
- II. Claims 38-39, 42-64, 74-99 drawn to a method of identifying a target for antibacterial agents using a genetic screen, classified in class 435, subclass 6.
- III. Claim 40 drawn to a method of identifying a target for antibacterial agents using an immunoprecipitation assay, classified in class 435, subclass 7.1.
- IV. Claim 40, drawn to a method of identifying a target for antibacterial agents using a protein-protein crosslinking assay, classified in class 435, subclass 7.8.
- V. Claim 41-44, 54-58, and 92, drawn to a method of identifying the bacterial coding sequence of a bacterial target, classified in class 435, subclass 7.32.

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- VI. Claims 48-52, 74-91, drawn to a method of identifying a bacteriophage ORF encoding a bacterial inhibiting protein, classified in class 435, subclass 5.
 - VII. Claim 59, drawn to a method determining the cellular or biochemical function of said inhibitor protein, classified in class 435, subclass 5.
 - VIII. Claim 60, drawn to a method of identifying the phage specific site of action of the bacterial target, classified in class 435, subclass 7.32.
3. Claim 9 link(s) inventions I-VIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 9. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Furthermore, Applicants are required to elect one of the bacterial species or strains or Table 1, one of the uncharacterized bacteriophage listed in Table 1, and one of the bacterial species of Claims 65-73 as part of the restriction requirement.

The inventions are distinct, each from the other because of the following reasons:

1. Inventions I-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different methods of screening for interactions between a bacterial target protein(s) and bacteriophage inhibitor proteins.

Group I is drawn to protein binding or affinity assays, and do not involve or require the use of antibodies, as in Group III; crosslinking reagents, as in Group IV; or DNA, as in Groups II, V, and VI; for its practice. As such, the methods would be practiced using reagents and under conditions that would be unique to each method. Thus, each of Groups I, II, III, IV, V, and VI has a mode of operation that is distinct from the other.

The method of Group I also has a function that is different from the methods of Groups VII and VIII. The method of Group I only assays from protein-protein binding, it does not identify the cellular or biochemical function of the bacterial inhibitor protein, nor does it identify the specific site of action of the bacterial target. Likewise, none of Groups II-VI can identify the properties of the bacterial inhibitor protein, or the site of action of the bacterial target, as in Groups VII and VIII. The method of Group II utilizes a genetic screen to identify the bacterial target. That of Group III employs an immunoprecipitation assay, while Group IV employs a protein-protein crosslinking assay. Group V identifies the nucleic acid sequence encoding the bacterial target, while Group VI identifies the bacteriophage ORF that encodes the bacterial inhibiting protein. Thus, Groups II-VI likewise are drawn to different functions and yield different results from the methods of Groups VII and VIII.

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2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art, the search required for one Group would not be required for any other Group. These inventions have acquired a separate status in the art because of their recognized divergent subject matter, therefore, restriction for examination purposes as indicated is proper.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Tu whose telephone number is 703-308-3968. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 703-308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

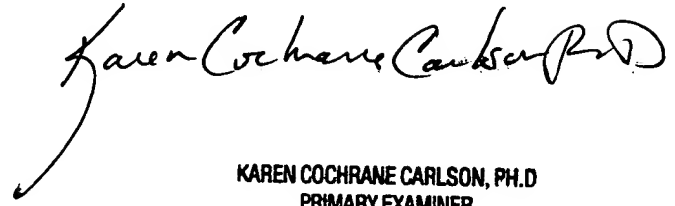
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

ST
March 12, 2001

A handwritten signature in cursive script, reading "Karen Cochrane Carlson PhD". The signature is written in black ink and is positioned above the printed name and title.

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER